VAPRENA®
Tolvaptan

Patient Alert Card

Safety advice for patients taking Vaprena (Tolvaptan)
Please keep this card with you at all times

Reporting of Side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Adverse events can also be reported to: SFDA-National Pharmacovigilance and Drug Safety Center

- **Email:** npc.drug@sfda.gov.sa
- **Website:** http://ade.sfda.gov.sa
- **Direct phone:** 19999

Further Information: For further information, please contact SPIMACO on Tel: +966 11252 3393 or by email GPV@spimaco.sa

By reporting side effects, you can help provide more information on the safety of this medicine.

Patient's name: _____

Date Tolvaptan first prescribed: _____

Doctor's name: _____

Treatment Centre name: _____

Treatment Centre contact number: _____

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Important safety information for patients
Vaprena (Tolvaptan) can affect how your liver works

Your doctor will arrange blood tests for liver function testing:
- Before starting treatment with Tolvaptan.
- Monthly for the first 18 months of treatment
- Then every 3 months thereafter

Consult your doctor immediately if you experience symptoms of tiredness, loss of appetite, pain in the abdomen, dark urine, yellowing of skin or eyes (jaundice), severe dehydration, nausea, vomiting, fever, itching of your skin or flu-like syndrome (joint and muscle pain with fever).

You should not take Tolvaptan if you are trying to become pregnant or during pregnancy, as it may result in side effects to you and developmental abnormalities in your unborn baby.

Women of childbearing potential must use one effective method of pregnancy prevention for at least 4 weeks before starting therapy, during therapy and for at least a further 4 weeks after stopping Tolvaptan.

You should discuss with your physician the most suitable form of contraception to use.